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American Medical Systems, Inc.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JULIE KRASAUSKAS and WILLIAM KRASAUSKAS,

SHANNON GRAY,

JENNIFER DEGEARE and COREY DEGEARE,

MARCEL HALL,

SHELIA HOOVER and BILL HOOVER,

KAREN KING,

NICKOL HARSGRAVE,

PATSY SMITH,

TINA MARIE LEE,

SHERRY BOYLAN and MARSHALL BRICE BOYLAN,

FANNIE BELLOW and LAWRENCE BELLOW,

CYNTHIA CRAIN and THOMAS CRAIN,

Plaintiffs,

vs.

AMERICAN MEDICAL SYSTEMS, INC.,

Defendant.

CASE NO. C 12 5463 NC

[Removal from Superior Court of California, San Francisco County, Case No.: CGC-12-517793]

DEFENDANT AMERICAN MEDICAL SYSTEMS, INC.'S NOTICE OF REMOVAL OF ACTION UNDER 28 U.S.C. SECTIONS 1332, 1441, AND 1367 (DIVERSITY AND SUPPLEMENTAL JURISDICTION); DEMAND FOR JURY TRIAL

[Filed concurrently with Corporate Disclosure Statement and Certification of Interested Parties]

TO THE CLERK OF THE UNITED STATES DISTRICT COURT OF THE NORTHERN DISTRICT OF CALIFORNIA:

PLEASE TAKE NOTICE that Defendant American Medical Systems, Inc. ("AMS") hereby removes to this Court the state court action described below.

I. JURISDICTION

1. Removal is warranted under 28 U.S.C. § 1441 because this is a diversity action over which this Court has original jurisdiction under 28 U.S.C. § 1332 of the claims of Plaintiffs alleging product liability claims and supplemental jurisdiction under 28 U.S.C. § 1367 over the remaining Plaintiffs alleging claims for loss of consortium. Complete diversity of citizenship exists among the parties and the amount in controversy exceeds the sum of $75,000.00, exclusive of interest and costs, as explained more fully below.

II. INTRADISTRICT ASSIGNMENT

2. The San Francisco Division of this Court is the appropriate assignment for this action as the state court action described below is currently pending in San Francisco County.

III. PROCEDURAL HISTORY

3. On January 31, 2012, an action was commenced against AMS in the Superior Court of the State of California, County of San Francisco, entitled *Julie Krasauskas, et al., v. American Medical Systems, Inc., et al.*, as Case No. CGC-12-517793. A true and correct copy of the Complaint is attached hereto as **Exhibit A** ("Complaint"). Twelve of the Plaintiffs in this action are women who allege a variety of injuries from the surgical implantation of AMS pelvic surgical mesh devices (the "Device

Recipient Plaintiffs"). The remaining six Plaintiffs are spouses of certain of the Device Recipient Plaintiffs who have alleged loss of consortium claims.

4. AMS received a copy of the Complaint in this action on April 4, 2012, when a copy of the Summons and Complaint was served by way of certified mail at AMS's offices in Minnetonka, Minneapolis. A true and correct copy of the Service of Process Transmittal is attached hereto as **Exhibit B**.

5. On May 17, 2012, AMS filed its Answer to Plaintiffs' Complaint. A true and correct copy of AMS's Answer is attached hereto as **Exhibit C**.

6. This action has been set for trial on November 12, 2013.

7. On June 6, 2012, AMS served its Special Interrogatories, Set One and Form Interrogatories on Plaintiffs, seeking, among other things, information regarding Plaintiffs' residences and domiciles. On August 10, 2012, Plaintiffs served their Responses to AMS's Special Interrogatories and Form Interrogatories, but objected to providing any information regarding their residences or domiciles. After efforts to meet and confer with Plaintiffs' counsel were unsuccessful, AMS filed a motion to compel further interrogatory responses on September 28, 2012. After which, Plaintiffs provided amended responses to only AMS' Special Interrogatories on October 9, 2012, which identified their domiciles. As discussed below, this was AMS's first receipt of a paper from which it was ascertainable that this case is removable. *See* 28 U.S.C. ¶ 1446(b). A true and correct copy of Plaintiffs' amended Responses to AMS's Special Interrogatories, Set One is attached hereto as **Exhibit D**.

8. Attached as **Exhibit E** is a true and correct copy of the documents in the San Francisco Superior Court file regarding this action, which includes all pleadings, process, and orders served on AMS.[1]

9. This is one of many product liability actions that have been filed across the country involving various models of pelvic surgical mesh devices manufactured by AMS. On February 7, 2012, the Judicial Panel on Multidistrict Litigation ("JPML") issued an order transferring 84 AMS pelvic surgical mesh device-related cases to the United States District Court for the Southern District of West

[1] Due to the volume of documents, the Declaration of Tiffany M. Bui in support of AMS' September 28, 2012 Motion to Compel is not included in Exhibit E.

Virginia for coordinated pretrial proceedings under 28 U.S.C. § 1407. AMS intends to seek the transfer of this action to that Multidistrict Litigation, *In re: American Medical Systems, Inc., Pelvic Repair System Products Liability Litigation American Medical, Inc.*, MDL 2325, (the "AMS MDL"), in which there is now well over a thousand cases, and AMS will provide the JPML with notice of this action pursuant to the procedure for "tag along" actions set forth in the rules of the JPML.

10. As more fully set forth below, this case is properly removed to this Court pursuant to 28 U.S.C. §1441 because this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332 and §1367 and AMS has satisfied the procedural requirements for removal.

IV. REMOVAL IS PROPER IN THIS ACTION

A. Diversity of Citizenship

11. AMS was, at the time the Complaint was filed, and continues to be a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in the State of Minnesota. Accordingly, AMS is a citizen of the States of Delaware and Minnesota for diversity purposes. *See* 28 U.S.C. § 1332(c)(1).

12. None of the Plaintiffs is or was a citizen of Delaware or Minnesota. Plaintiffs' citizenships were, at the time the Complaint was filed, and continue to be as follows:

- Plaintiffs Julie Krasauskas and William Krasauskas are citizens of Ohio (Plaintiffs' amended Special Interrogatory Responses, **Exhibits D-1 and D-2**);
- Plaintiff Shannon Gray is a citizen of Indiana (*Id.*, **Exhibit D-3**);
- Plaintiffs Jennifer Degeare and Corey Degeare are citizens of Oklahoma (*Id.*, **Exhibits D-4 and D-5**);
- Plaintiff Marcel Hall is a citizen of Texas (*Id.*, **Exhibit D-6**);
- Plaintiffs Sheila Hoover and Bill Hoover are citizens of Arizona (*Id.*, **Exhibits D-7 and D-8**);
- Plaintiff Karen King is a citizen of Michigan (*Id.*, **Exhibit D-9**);

- Plaintiff Nickol Hargrave is a citizen of Alabama (*Id.*, **Exhibit D-10**);
- Plaintiff Patsy Smith is a citizen of Colorado (*Id.*, **Exhibit D-11**);
- Plaintiff Tina Marie Lee is a citizen of Alabama (*Id.*, **Exhibit D-12**);
- Plaintiffs Sherry Boylan and Marshall Boylan are citizens of Washington (*Id.*, **Exhibits D-13 and D-14**);
- Plaintiffs Fannie Bellow and Lawrence Bellow are citizens of Louisiana (*Id.*, **Exhibits D-15 and D-16**); and;
- Plaintiffs Cynthia Crain and Thomas Crain are citizens of Pennsylvania (*Id.*, **Exhibits D-17 and D-18**).

13. Consequently, there is complete diversity between all Plaintiffs and AMS.

B. Timeliness of Notice of Removal

14. This Notice of Removal is timely under 28 U.S.C. § 1446(b) because AMS is filing this Notice of Removal within 30 days of its receipt of a "paper from which it may first be ascertained that the case is one which is or has become removable." 28 U.S.C. § 1446(b)(3).

15. The Complaint fails to provide any information regarding the domicile, citizenship, or residency of any of Plaintiffs that would provide a basis for diversity jurisdiction. Accordingly, the 30 day removal period did not begin to run with the service of the Complaint because it was not ascertainable from the Complaint that this case is removable. *See Harris v. Bankers Life & Cas. Co.*, 425 F.3d 689, 693 (9th Cir. 2005).

16. Likewise, Plaintiffs' Responses to AMS' Special Interrogatories and Form Interrogatories failed to provide any information regarding the domicile, citizenship, or residency of any of Plaintiffs that would provide a basis for diversity jurisdiction because Plaintiffs simply objected to providing any information regarding Plaintiffs' domiciles or residences.

17. Plaintiffs' amended Responses to AMS's Special Interrogatories, Set One identified each of Plaintiffs' domiciles and provided the first paper from which it could be ascertained that this case is removable. AMS received those amended responses on October 9, 2012, and therefore, this Notice of

Removal was filed within the 30 removal period provided by 28 U.S.C. § 1446(b)(3). *See Lovern v. General Motors, Corp.*, 121 F.3d 160, 161 (4th Cir. 1997)(evidence of diversity of citizenship first provided in interrogatory responses of plaintiff).

18. Likewise, this Notice of Removal was filed within one year of the January 31, 2012 commencement of this action in accordance with 28 U.S.C. § 1446(b).

C. The Amount in Controversy Requirement

19. It is apparent from the face of the Complaint that each of the Device Recipient Plaintiffs seeks recovery of an amount in excess of $75,000, exclusive of costs and interest. Each of the Plaintiffs implanted with an AMS pelvic surgical mesh device alleges a wide variety of injuries caused by the implantation of the devices, specifically, "serious bodily injuries, including, but not limited to, extreme pain, erosion of their internal bodily tissue, dyspareunia, additional surgery and other injuries." (Complaint, ¶ 66.) The Complaint also states that as a result of an allegedly defective AMS pelvic surgical mesh devices, the Device Recipient Plaintiffs have undergone "significant mental and physical pain and suffering, have required additional surgery and medical treatment and have sustained permanent injury." (Complaint, ¶ 68.) These alleged injuries further include "mesh erosion, hardening, chronic pain, worsening dyspareunia, and recurrent incontinence leading to the need for dangerous and serious vaginal surgery." (Complaint, ¶ 75.)

20. The Device Recipient Plaintiffs also allege that Plaintiffs "were required to and employed health care providers and incurred medical, hospital and incidental expenses; further, Plaintiffs are informed and believe, and allege thereon, that Plaintiffs will be required to incur additional medical, hospital, and incidental expenses. . . ." (Complaint, ¶ 70.) Plaintiffs further allege that they "have suffered a loss of earnings and earning capacity and will continue to suffer a loss of future earnings. . . ." (Complaint, ¶ 71.)

21. The Device Recipient Plaintiffs further allege punitive damages claiming that AMS acted with "oppression, fraud, and malice." (Complaint, ¶¶ 76, 101, 107.)[2]

22. Where, as here, the plaintiffs do not allege a specific amount of damages in the Complaint, the District Court may "examine the complaint to determine whether it is 'facially apparent' that the claims exceed the jurisdictional amount." *White v. FCI USA, Inc.*, 319 F.3d 672, 675 (5th Cir. 2003). To ascertain the amount in controversy, a court takes into account claims for general damages, pain and suffering, out-of-pocket loss, emotional distress, punitive damages and attorney's fees. *Richmond v. Allstate Ins. Co.*, 897 F. Supp. 447, 449-50 (S.D. Cal. 1995). In addition, in measuring the amount in controversy, a court should assume that the allegations of the complaint are true and assume that a jury will return a verdict for the plaintiff on all claims made in the complaint. *See Kenneth Rothschild Trust v. Morgan Stanley Dean Witter*, 199 F. Supp. 2d 993, 1001 (C.D. Cal. 2002). Moreover, "the amount in controversy is not measured by the low end of an open-ended claim, but rather by reasonable reading of the value of the rights being litigated." *See id.* (quoting *Angus v. Shiley*, 989 F.2d 142, 146 (3d Cir. 1993)).

23. Plaintiffs' allegations in the Complaint demonstrate that the amount in controversy requirement is satisfied. Each claims serious mental and physical injuries, including permanent injuries, that have allegedly caused them severe pain, further surgeries, and additional medical treatment. These injuries are also alleged to have required, and will require, them to incur medical, hospital, and incidental expenses, as well as past and future lost earnings.

24. Furthermore, their claims for punitive damages make it apparent that the jurisdictional minimum has been met in this action. *See Gibson v. Chrysler Corp.*, 261 F.3d 927, 945 (9th Cir. 2001).

25. Additional evidence that the amount in controversy requirement is satisfied in this action are the many other AMS pelvic surgical mesh device cases, all making similar allegations to those made by Plaintiffs here, that were initially filed in federal court, or removed to federal court, and were then transferred by the JPML to the Southern District of West Virginia as part of the AMS MDL. *See In re Rezulin Products Liab. Litig.*, 133 F. Supp. 2d 272, 296 (S.D.N.Y. 2001) (finding amount in controversy

[2] More specifically, each of the Device Recipient Plaintiffs prays for recovery of "general damages," "medical, hospital, and incidental expenses," "loss of earnings and loss of earning capacity," "punitive or exemplary damages," and "other relief as the Court deems proper." (Complaint at pp. 32-35).

requirement satisfied, *inter alia*, based on fact that "[o]ther complaints in this MDL allege damages" in excess of jurisdictional amount). Indeed, there are numerous cases brought by Plaintiffs' counsel in this action pending in the AMS MDL in which the same type of personal injury allegations regarding AMS pelvic surgical mesh devices met the amount in controversy requirement.

26. The claimed injuries in these cases establish that it is more likely than not that claims of serious pelvic injury from the alleged effects of a medical device lead to an amount in controversy that exceeds $75,000, exclusive of interest and costs, meeting the jurisdictional amount in controversy required by 28 U.S.C. § 1332(a).[3]

27. Furthermore, the claims of the remaining eight Plaintiffs who are alleging loss of consortium damages are subject to the jurisdiction of this Court under the supplemental jurisdiction provisions of Section 1367 of Title 28 of the United States Code ("Section 1367"). Section 1367 provides that when a federal court has jurisdiction over a civil action, it also has supplemental jurisdiction over all claims that are "so related to claims in the action within such original jurisdiction that they form part of the same case or controversy." 28 U.S.C. § 1367(a). Consequently, Section 1367 provides federal jurisdiction over a loss of consortium claim that might not meet the requirements of diversity jurisdiction if the personal injury claim giving rise to the loss of consortium claim meets the requirements of diversity jurisdiction. *Monroe v. Brown*, 256 F. Supp. 2d 1292, 1293-94 (M. D. Ala. 2003).

V. AMS HAS MET THE PROCEDURAL REQUIREMENTS FOR REMOVAL

28. AMS will give written notice of the filing of this Notice of Removal as required by 28 U.S.C. § 1446(d).

29. A copy of this Notice of Removal will be filed with the Clerk of the Superior Court of the State of California for the County of San Francisco as required by 28 U.S.C. § 1446(d).

30. No previous request has been made for the relief requested herein.

[3] In alleging the amount in controversy for purposes of removal, AMS does not concede in any way that the allegations in the Complaint are accurate or true or that Plaintiffs are entitled to any relief whatsoever.

31. There is no other named defendant for which consent to remove would be required.

32. This Notice of Removal is properly filed in the Northern District of California pursuant to 28 U.S.C. § 1446(a).

33. The United States District Court for the Northern District of California embraces the county in which the state court action is now pending. Therefore, this Court is a proper venue for removal of this action pursuant to 28 U.S.C. §§ 104(a) &1441(a).

WHEREFORE, AMS respectfully removes this action from the Superior Court of the State of California in and for the County of San Francisco to this Honorable Court, pursuant to 28 U.S.C. §§1441 and 1367.

DATED: October 22, 2012. REED SMITH LLP

By _____
J. David Bickham
Tiffany M. Bui
Attorneys for Defendant
American Medical Systems, Inc.

DEMAND FOR JURY TRIAL

Defendant American Medical Systems, Inc. hereby demands trial by jury in this action.

DATED: October 22, 2012. REED SMITH LLP

By _____
J. David Bickham
Tiffany M. Bui
Attorneys for Defendant
American Medical Systems, Inc.

EXHIBIT A

SUMMONS ISSUED

FILED
Superior Court of California
County of San Francisco
JAN 31 2012
CLERK OF THE COURT
BY: Elias Ruiz Deputy Clerk

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

JULIE KRASAUSKAS and WILLIAM KRASAUSKAS,

SHANNON GRAY,

JENNIFER DEGEARE and COREY DEGEARE,

MARCEL HALL,

SHELIA HOOVER and BILL HOOVER,

KAREN KING,

NICKOL HARSGRAVE,

PATSY SMITH,

TINA MARIE LEE,

SHERRY BOYLAN and MARSHALL BRICE BOYLAN,

FANNIE BELLOW and LAWRENCE BELLOW,

CASE NUMBER: CGC-12-517793

COMPLAINT AND DEMAND FOR JURY TRIAL [PRODUCTS LIABILITY]

1. **Strict Liability-Failure to Warn**
2. **Strict Liability**
3. **Negligence**
4. **Breach of Implied Warranty**
5. **Breach of Express Warranty**
6. **Fraud**
7. **Fraud by Concealment**
8. **Negligent Misrepresentation**
9. **Loss of Consortium**

CYNTHIA CRAIN and THOMAS CRAIN,

Plaintiffs,

vs.

AMERICAN MEDICAL SYSTEMS, INC.,

Defendants.

DEMAND FOR JURY TRIAL

1.

Plaintiffs herewith request a trial by jury as to all issues to all material facts.

PARTIES

2.

Plaintiffs JULIE KRASAUSKAS and WILLIAM KRASAUSKAS are husband and wife.

3.

Plaintiff SHANNON GRAY is a single woman.

4.

Plaintiffs JENNIFER DEGEARE and COREY DEGEARE are husband and wife.

5.

Plaintiff MARCEL HALL is a single woman.

6.

Plaintiffs SHELIA HOOVER and BILL HOOVER are husband and wife.

7.

Plaintiff KAREN KING is a single woman.

8.

Plaintiff NICKOL HARSGRAVE is a single woman.

9

Plaintiff PATSY SMITH is a single woman.

10.

Plaintiff TINA MARIE LEE is a single woman.

11.

Plaintiffs SHERRY BOYLAN and MARSHALL BOYLAN are husband and wife.

12.

Plaintiffs FANNIE BELLOW and LAWRENCE BELLOW are husband and wife.

13.

Plaintiffs CYNTHIA CRAIN and THOMAS CRAIN, SR., are husband and wife.

14.

Defendant American Medical Systems (AMS) develops technology to diagnose and treat conditions related to the pelvic health of women. At all times relevant herein, AMS was engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the AMS Apogee System with IntePro ("Apogee"), Perigee System with IntePro ("Perigee") and Monarc Subfascial Hammock. ("Monarc") American Medical Systems manufactures, markets, advertises, promotes and sells Apogee, Perigee and Monarc ("Pelvic Mesh Products") worldwide. Defendant manufactures medical devices in California. None of the defendants reside in California.

FACTUAL ALLEGATIONS

15.

Prior to and in 2004, Defendant sought and obtained Food and Drug Administration ("FDA") approval to market the Pelvic Mesh Products under Section 510(k) of the Medical Device Amendment. Section 501(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

16.

The Pelvic Mesh Products are products targeted at women who suffer from pain, discomfort, and stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. The Pelvic Mesh Products are represented by defendant to correct and restore normal vaginal structure by implantation of polypropylene mesh in the vaginal wall tethered in place by two arms that extend up through the buttocks. It is specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

17.

Moreover, these Pelvic Mesh Products contain a monofilament polypropylene mesh intended for the treatment of stress urinary incontinence. Despite claims that this material is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendant's Pelvic Mesh Products containing this material. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

18.

Defendant's Pelvic Mesh Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

19.

The Defendant has marketed and sold the Pelvic Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Also utilized are documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the products.

20.

At all times relevant to this action, Defendant, intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages the Pelvic Mesh Products and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as a safe medical device when, in fact, Defendant, knew that the Pelvic Mesh Products were not safe for their intended purposes and that the Pelvic Mesh Products would cause, and did cause, serious medical problems, and in some patients, catastrophic and permanent injuries.

21.

Contrary to the Defendant's representations and marketing to the medical community and to the patients themselves, the Defendant's Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiffs, making them defective under the law. The defects stem from any or all of the following:

a. the use of polypropylene material in the Mesh itself and the immune

reaction that results, causing adverse reactions and injuries;

b. the design of the Pelvic Mesh Devices to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade resulting in injury

d. the use and design of anchors in the Pelvic Mesh Products which when placed correctly are likely to pass through and injury major nerve routes in the pelvic region.

d. degradation of the mesh itself over time which causes the internal tissue to degrade resulting in injury.

e. the welding of the mesh itself during production which creates a toxic substance that contributes to the degradation of the mesh and host tissue alike.

f. the design of trocars, as devices to insert the Pelvic Mesh Products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries.

22.

The Defendant has consistently underreported and withheld information about the propensity of Defendant's Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

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23.

Despite the chronic underreporting of adverse events associated with the Defendant's Pelvic Mesh Products and the underreporting of events associated with similarly designed competitor products, enough complaints were recorded for the FDA to issue a public health notification regarding the dangers of these devices.

24.

On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to pelvic mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendant is one of the manufacturers of the products that are the subject of the notification.

25.

On July 13, 2011, the FDA issued a Safety Communication:" UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse" Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of Pelvic Organ Prolapse was an area of **"continuing serious concern."** (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of Pelvic Organ Prolapse, were "not rare." These serious complications include, but are not limited to neuromuscular problems, vaginal scarring/shrinkage and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of Pelvic Organ Prolapse with mesh or repair of SUI with mesh kits was more effective than traditional non mesh repair of pelvic organ prolapse. The FDA conducted a systematic review of the published scientific literature

from 1996-2011 and concluded that based thereon, that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011 Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13 2011 was known or knowable to defendant and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions for use or labeling.

26.

Defendant has known that some of the predicate products for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices(including a medical device known as Protogen device); that there were and are differences between the Defendant's Pelvic Mesh Products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; that significant differences exist and existed between the Pelvic Mesh Products and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and that the Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. The Defendant suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the Defendant actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Pelvic Mesh Products and the procedures for implantation were and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into the Plaintiffs.

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27.

Defendant failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of its Pelvic Mesh Products.

28.

Defendant failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Pelvic Mesh Products.

29.

Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the Defendant's Pelvic Mesh Products.

30.

The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to the Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

31.

The Defendant provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of the Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiffs.

32.

The Pelvic Mesh Products implanted into the Plaintiffs were in the same or substantially similar condition as they were when they left the possession of Defendant, and in the condition directed by and expected by the Defendant.

33.

Plaintiffs and their physicians foreseeably used and implanted the Pelvic Mesh Products, and did not misuse, or alter the Products in an unforeseeable manner.

34.

The injuries, conditions, and complications suffered by women who have been implanted with Defendant's Pelvic Mesh Products include but are not limited to mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

35.

The Medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendant's Pelvic Mesh, have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

36.

Defendant misrepresented to the medical and healthcare community, Plaintiffs, the FDA, and the public that the Products had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse.

37.

These representations were made by Defendant with the intent of inducing the medical community, Plaintiffs, and the public, to recommend, prescribe, dispense, and purchase the Products for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced an indifference to the health, safety, and welfare of Plaintiffs.

38.

Defendant failed to undertake their duties to properly know the qualities of their

products and in representations to Plaintiffs and/or to Plaintiffs' healthcare providers, to and concealed and intentionally omitted the following material information:

a. That the Products were not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. That the risk of adverse events with the Products was higher than with other products and procedures available to treat incontinence and/or prolapse;

c. That the risk of adverse events with the Products were not adequately tested and were known by Defendant;

d. That the limited clinical testing revealed the Products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

e. That Defendant failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

f. That Defendant was aware of dangers in the Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

g. That the Pelvic Mesh Products were dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

h. That patients needed to be monitored more regularly than usual while using the Products and that in the event the products needed to be removed that the

procedures to remove them had a very high failure rate and/or needed to be performed repeatedly; Thus:

i. That the Products were manufactured negligently;

j. That the Products were manufactured defectively;

k. That the Products were designed negligently, and designed defectively.

39.

Defendant was under a duty to disclose to Plaintiffs and their physicians, the defective nature of the Products, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

40.

Defendant had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Pelvic Mesh Products.

41.

Defendant's concealment and omissions of material fact concerning the safety of the Pelvic Mesh Products were made to cause Plaintiffs' physicians and healthcare providers to purchase, prescribe, and/or dispense the Products; and/or to mislead Plaintiffs into reliance and cause Plaintiffs to use the Products.

42.

At the time these representations were made by Defendant, and at the time Plaintiffs used the Products, Plaintiffs were unaware of the falsehood of these representations, and reasonably believed them to be true.

///

43.

Defendant knew and had reason to know that the Products could and would cause severe and grievous personal injury to the users of the Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

44.

In reliance upon these false representations, Plaintiffs were induced to, and did use the Pelvic Mesh Products, thereby sustaining severe and permanent personal injuries and damages. Defendant knew or had reason to know that Plaintiffs and their physicians and other healthcare providers had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding the use of the Products, as described in detail herein.

45.

As a result of Defendant's research and testing or lack thereof, Defendant distributed false information, including but not limited to assuring Plaintiffs, the public, and Plaintiffs' healthcare providers and physicians, that the Products were safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiffs, and the public at large.

46.

Defendant had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers, and the FDA.

47.

The information distributed to the public, the medical community, the FDA, and Plaintiffs by Defendant included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Products.

48.

Defendant intentionally made material misrepresentations to the medical community and public, including Plaintiffs, regarding the safety of the Products specifically that the Products did not have dangerous and/or serious adverse health safety concerns, and that the Products were as safe as other means of treating vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

49.

Defendant intentionally failed to inform the public, including Plaintiffs, of the high failure rate including erosion, the difficulty of removing the mesh, and the risk of permanent injury.

50.

Defendant chose to over-promote the safety, efficacy and benefits of the Products instead.

51.

Defendant's intent and purpose in making these misrepresentations was to deceive the public, the medical community, and Plaintiffs; to gain the confidence of the public, the medical community, and Plaintiffs; to falsely assure them of the quality and fitness for use of the

Products; and induce Plaintiffs, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Products.

52.

Defendant made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Products did not present serious health risks.

53.

These representations, and others made by Defendant, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

These representations, and others made by Defendant, were made with the intention of deceiving Plaintiffs, Plaintiffs' healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiffs, and their respective healthcare professionals, to rely on misrepresentations, and caused Plaintiffs to purchase, rely, use, and request the Products and their healthcare professionals to dispense, recommend, or prescribe the Products.

54.

Defendant recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Products to the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives. Defendant utilized direct-to-consumer advertising to market, promote, and advertise the Products.

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55.

At the time the representations were made, Plaintiffs and their healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Products. Plaintiffs did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiffs discover the false representations of Defendant, nor would Plaintiffs with reasonable diligence have discovered the true facts or Defendant's misrepresentations.

56.

Had Plaintiffs known the true facts about the dangers and serious health and/or safety risks of the Pelvic Mesh Products, Plaintiffs would not have purchased, used, or relied on Defendant's products.

57.

At all times relevant herein, the Pelvic Mesh Products were widely advertised and promoted by the Defendant , as a safe and effective treatment for vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele. Defendant minimized the risks posed to rectocele and vaginal prolapse patients with implantation of the Pelvic Mesh Products.

58.

At all times relevant to this action, Defendant knew that the Pelvic Mesh Products were not safe for the patients for whom they were prescribed and implanted, because the mesh eroded and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing injuries from erosion, extrusion, infection, sepsis, chronic foreign body invasion, dense adhesions and worsening dyspareunia. Removal of eroded or infected mesh brings a high rate of life-threatening complications including permanent disfigurement and hemorrhage. Removal can require multiple surgical interventions in the operating theater for complete removal and results in scarring on fragile compromised pelvic tissue and muscles.

59.

At all relevant times herein, Defendant continued to promote Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short-term efficacy.

60.

In doing so the Defendant concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Pelvic Mesh Products for treatment of vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

61.

At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiffs and the general public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products system including, but not limited to, mesh erosion, dense adhesions, worsening dyspareunia, chronic pain, infection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

62.

The Pelvic Mesh Products as designed, manufactured, distributed sold and/or supplied by Defendant were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants knowledge of lack of pelvic health safety.

63.

At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew of the hazards and dangerous propensities of said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiffs.

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PLAINTIFFS' EXPERIENCE AND INJURIES

64.

Plaintiffs were implanted with Defendant's Pelvic Mesh Product, which was designed, manufactured, packaged, labeled and sold by Defendant.

65.

At all times that the Pelvic Mesh Product were implanted in Plaintiffs, the Pelvic Mesh Product was being used for the purposes that Defendant marketed the products.

66.

After, and as a result of the implantation of the Pelvic Mesh Product, Plaintiffs suffered serious bodily injuries, including, but not limited to, extreme pain, erosion of their internal bodily tissue, dyspareunia, additional surgery and other injuries. These injuries would not have occurred but for the defective nature of the products implanted and/or Defendant's wrongful conduct.

67.

Within one year last past, Plaintiffs saw for the first time, televised information about product safety and defect issues associated with the implantation of Pelvic Mesh Products. After seeing this information, Plaintiffs suspected for the first time that the Pelvic Mesh Product that had been implanted into them may have been defective and that Plaintiffs may have sustained injuries as a result of having had Defendant's defective Pelvic Mesh Product implanted into them.

68.

As a result of having the Pelvic Mesh Product implanted into their bodies, Plaintiffs have experienced significant mental and physical pain and suffering, have required additional surgery and medical treatment and have sustained permanent injury.

69.

As a result of the aforesaid conduct and defective product manufactured, sold, distributed, advertised, and promoted by Defendant, Plaintiffs were injured in their health, strength, and activity, sustaining injury to their person, all of which injuries have caused Plaintiffs severe mental and physical pain and suffering. Plaintiffs are informed and believe, and allege thereon, that such injuries will result in some permanent disability to their bodies. As a result of such injuries, Plaintiffs have suffered general damages in an amount within the jurisdiction of the state court.

70.

As a further result of the aforesaid conduct and defective product manufactured, sold, distributed, advertised, and promoted by Defendant, Plaintiffs were required to and employed health care providers and incurred, medical, hospital and incidental expenses; further, Plaintiffs are informed and believe, and allege thereon, that Plaintiffs will be required to incur additional medical, hospital, and incidental expenses thereto, all according to proof.

71.

As a further result of the aforesaid conduct and defective product manufactured, sold, distributed, advertised, and promoted by Defendant, Plaintiffs have suffered a loss of earnings and earning capacity and will continue to suffer a loss of future earnings, according to proof.

FIRST CAUSE OF ACTION

[Strict Product Liability - Failure to Warn]

72.

Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every

allegation contained in Paragraphs 1-71, inclusive, of this Complaint.

73.

Defendant, manufactured, sold and/or distributed the Pelvic Mesh Products to Plaintiffs to be used for treatment of vaginal prolapse, stress urinary incontinence or rectocele.

74.

At all times mentioned herein, the Pelvic Mesh Products were and are, dangerous and presented a substantial danger to patients who were implanted with the Pelvic Mesh Devices, and these risks and dangers were known or knowable at the time of distribution and implantation in Plaintiffs. Ordinary consumers would not have recognized the potential risks and dangers the Pelvic Mesh Products posed to pelvic reconstruction patients because its uses was specifically promoted to improve the health of such patients. The Pelvic Mesh Products were used in a way reasonably foreseeable to Defendant by Plaintiffs. Defendant failed to provide warnings of such risks and dangers to Plaintiffs as described herein.

75.

As a result of the implantation of the Pelvic Mesh Products Plaintiffs suffered debilitating injuries including mesh erosion, hardening, chronic pain and worsening dyspareunia, and recurrent incontinence leading to the need for dangerous and serious vaginal surgery.

76.

In doing the acts herein described, the Defendant acted with oppression, fraud and malice, and Plaintiffs are therefore entitled to punitive damages to deter Defendant, and others from engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of the Defendant.

77.

WHEREFORE, Plaintiffs pray for judgment against Defendant as hereinafter set forth.

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SECOND CAUSE OF ACTION

[Strict Liability]

78.

Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-77, inclusive, of this Complaint.

79.

The Pelvic Mesh Products were manufactured and/or supplied by the Defendant, and were placed into the stream of commerce by the Defendant in a defective and unreasonably dangerous condition in that the foreseeable risks exceeded the benefits associated with its design of formulation.

80.

Alternatively, Pelvic Mesh Products manufactured and/or supplied by the Defendant were defective in design or formulation, inadequate warning or instruction and/or inadequate post-marketing warnings or instructions in that when it was placed in the stream of commerce, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other forms of stress urinary incontinence, pelvic organ prolapse or rectocele repair.

81.

As a result of the defective unreasonably dangerous condition of these products manufactured and/or supplied by the Defendant, Plaintiffs were caused to suffer the herein described injuries and damages.

82.

Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by Pelvic Mesh Products.

83.

Defendant, thereby acted with fraud, malice, oppression and a conscious disregard for the Plaintiffs and general public's safety, who accordingly requests that the trier of fact, in the

exercise of sound discretion, award additional damages for the sake of example and for the purpose of punishing the Defendant for its conduct, in an amount sufficiently large to be an example to others and deter the Defendant and others from engaging in similar conduct in the future. The aforesaid wrongful conduct was done with the advance knowledge, authorization, and/or ratification of an officer, director, and/or managing agent of Defendant.

WHEREFORE, Plaintiffs pray for judgment against Defendant, as hereinafter set forth.

THIRD CAUSE OF ACTION

[Negligence]

84.

Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-83, inclusive, of this Complaint.

85.

Defendant, and its representatives were manufacturers and/or distributors of Pelvic Mesh Products. At all times herein, Defendant had a duty to properly manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings and prepare for use and sell the aforesaid product.

86.

Defendant so negligently and carelessly manufactured, compounded, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied aforesaid product, that it was dangerous and unsafe for the use and purpose for which it was intended, that is, rectocele repair in Plaintiffs and others similarly situated. As a result of the carelessness and negligence of Defendant, Plaintiffs had the Pelvic Mesh Products described herein implanted in the manner intended by the manufacturer, and, as a result, Plaintiffs suffered the injuries and damages described herein..

WHEREFORE, Plaintiffs pray for judgment against Defendant as hereinafter set forth.

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FOURTH CAUSE OF ACTION

[Breach of Implied Warranty]

87.

Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-86 inclusive, of this Complaint.

88.

Defendant, impliedly warranted that the Pelvic Mesh Products, which Defendant designed, manufactured, assembled, promoted and sold to Plaintiffs was merchantable and fit and safe for ordinary use. Defendant further impliedly warranted that its Pelvic Mesh Products were fit for the particular purpose of correcting urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele.

89.

Defendant's Pelvic Mesh Products were defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiffs to severe and permanent injuries. Therefore, Defendant breached the implied warranties of merchantability and fitness for a particular purpose when it's synthetic mesh system was sold to Plaintiffs, in that the Pelvic Mesh Products are defective and has eroded and caused dense scarring and otherwise failed to function as represented and intended.

90.

As a result of Defendant's breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiffs have sustained and will continue to sustain the injuries and damages described herein and is therefore entitled to compensatory damages.

91.

After Plaintiffs were made aware their injuries were a result of the aforesaid Pelvic Mesh Products, Defendant had ample and sufficient notice of the breach of said warranty.

WHEREFORE, Plaintiffs pray for judgment against Defendant as hereinafter set forth.

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FIFTH CAUSE OF ACTION

[Breach of Express Warranty]

92.

Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-91, inclusive, of this Complaint.

93.

Defendant expressly warranted to Plaintiffs and/or their authorized agents or sales representatives, in publications, and other communications intended for medical patients, and the general public, that the defective Pelvic Mesh Products were safe, effective, fit and proper for their intended use.

94.

Plaintiffs and Plaintiffs' physicians reasonably relied upon the skill and judgment of Defendant, and upon said express warranty, in using the aforesaid product. The warranty and representations were untrue in that the product caused severe injury to Plaintiffs and was unsafe and, therefore, unsuited for the use in which it was intended and caused Plaintiffs to sustain damages and injuries herein alleged.

95.

As soon as the true nature of the product, and the fact that the warranty and representations were false, were ascertained, said Defendant had ample and sufficient notice of the breach of said warranty.

WHEREFORE, Plaintiffs pray for judgment against Defendant as hereinafter set forth.

SIXTH CAUSE OF ACTION

[Fraud]

96.

Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-95, inclusive, of this Complaint.

///

97.

Defendant falsely and fraudulently represented to Plaintiffs, their physicians, and to members of the general public that the aforesaid product was safe, effective, reliable, consistent, and better than the other similar pelvic repair procedures when used in the manner intended by the manufacturer. The representations by said Defendant were in fact, false. The true facts include, but are not limited to that the aforesaid product was not safe to be used for treatment of urinary incontinence, pelvic organ prolapse, vaginal vault prolapse rectocele repair, and was, in fact, dangerous to the health and body of Plaintiffs.

98.

When the Defendant, made these representations, it knew that they were false. Defendant made said representations with the intent to defraud and deceive Plaintiffs, and with the intent to induce Plaintiffs to act in the manner herein alleged, that is to use the aforementioned product for treatment of urinary incontinence, pelvic organ prolapse, vaginal vault prolapse rectocele repair.

99.

At the time Defendant, made the aforesaid representations Plaintiffs took the actions herein alleged, Plaintiffs and their physicians were ignorant of the falsity of these representations and reasonably believed them to be true. In reliance upon said representations, Plaintiffs were induced to, and did, use the aforesaid product as herein described. If Plaintiffs had known the actual facts, they would not have taken such action. The reliance of Plaintiffs and their physicians upon Defendant's representations were justified because said representations were made by individuals and entities who appeared to be in a position to know the true facts.

100.

As a result of Defendant's fraud and deceit, Plaintiffs were caused to sustain the herein described injuries and damages.

///

101.

In doing the acts herein alleged, the Defendant acted with oppression, fraud, and malice, and Plaintiffs are therefore entitled to punitive damages to deter Defendant and others from engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of Defendant.

WHEREFORE, Plaintiffs pray for judgment against Defendant as hereinafter set forth.

SEVENTH CAUSE OF ACTION

[Fraud by Concealment]

102.

Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-101, inclusive, of this Complaint.

103.

At all times mentioned herein, Defendant had the duty and obligation to disclose to Plaintiffs and to their physicians, the true facts concerning the aforesaid Pelvic Mesh Products, that is, that said products were dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users including permanent and debilitating injuries. Defendant made the affirmative representations as set forth above to Plaintiffs and their physicians and the general public prior to the date Pelvic Mesh Products were implanted in Plaintiffs, while concealing material facts.

104.

At all times herein mentioned, Defendant, willfully, and maliciously concealed facts as set forth above from Plaintiffs and their physicians, and therefore, Plaintiffs, with the intent to defraud as herein alleged.

105.

At all times herein mentioned, neither Plaintiffs nor their physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they

did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized the Pelvic Mesh Products for correction of urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele. Defendant's representations were a substantial factor in Plaintiffs utilizing the Pelvic Mesh Products for correction of their medical condition.

106.

As a result of the concealment of the facts set forth above, Plaintiffs sustained injuries as hereinafter set forth.

107.

In doing the action herein alleged, Defendant acted with oppression, fraud, and malice and Plaintiffs are therefore entitled to punitive damages in an amount reasonably related to Plaintiffs' actual damages, and to Defendant's wealth, and sufficiently large to be an example to others, and to deter this Defendant, and others from engaging in similar conduct in the future.

WHEREFORE, Plaintiffs pray for judgment against Defendant as hereinafter set forth.

EIGHTH CAUSE OF ACTION

[Negligent Misrepresentation]

108.

Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-107, inclusive, of this Complaint.

109.

At all relevant times herein, Defendant represented to Plaintiffs and their physicians that the Pelvic Mesh Products were safe to use to correct stress urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele knowing that the Pelvic Mesh Products were defective and capable of causing the injuries described herein.

110.

The Defendant made the aforesaid representations with no reasonable ground for believing them to be true when defendants own data showed the Pelvic Mesh Products to be

defective and dangerous when used in the intended manner.

111.

The aforesaid representations were made to the physicians prescribing the Pelvic Mesh Products prior to the date it was prescribed to Plaintiffs and used by their physicians with the intent that Plaintiffs and their physicians rely upon such misrepresentations about the safety and efficacy of the Pelvic Mesh Products. Plaintiffs and their physicians did reasonably rely upon such representations that the aforesaid product was safe for use to correct stress urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele.

112.

The representations by said Defendant to Plaintiffs were false, and thereby caused Plaintiffs' injuries described herein.

WHEREFORE, Plaintiffs pray for judgment against Defendant as hereinafter set forth.

NINTH CAUSE OF ACTION
ON BEHALF OF WILLIAM KRASAUSKAS

[Loss of Consortium]

113.

Plaintiff WILLIAM KRASAUSKAS hereby incorporates by reference as if fully set forth herein, each and every allegation contained in paragraphs 1-112 of this Complaint.

114.

At all times herein mentioned, Plaintiffs WILLIAM KRASAUSKAS and JULIE KRASAUSKAS were husband and wife.

115.

As a direct result of Defendant's aforesaid conduct, Plaintiff WILLIAM KRASAUSKAS suffered a loss of love, affection, solace, moral support and physical assistance in the operation and maintenance of the home, all to his general damage in an amount within the jurisdiction of this Court.

WHEREFORE, Plaintiffs WILLIAM KRASAUSKAS and JULIE KRASAUSKAS

pray for judgment against Defendant as hereinafter set forth.

TENTH CAUSE OF ACTION
ON BEHALF OF COREY DEGEARE

[Loss of Consortium]

116.

Plaintiff COREY DEGEARE hereby incorporates by reference as if fully set forth herein, each and every allegation contained in paragraphs 1-112 of this Complaint.

117.

At all times herein mentioned COREY DEGEARE and JENNIFER DEGEARE were husband and wife.

118.

As a direct result of Defendant's aforesaid conduct, Plaintiff COREY DEGEARE suffered a loss of love, affection, solace, moral support and physical assistance in the operation and maintenance of the home, all to his general damage in an amount within the jurisdiction of this Court.

WHEREFORE, Plaintiffs COREY DEGEARE and JENNIFER DEGEARE pray for judgment against Defendant as hereinafter set forth.

ELEVENTH CAUSE OF ACTION
ON BEHALF OF BILL HOOVER

[Loss of Consortium]

119.

Plaintiff BILL HOOVER hereby incorporates by reference as if fully set forth herein, each and every allegation contained in paragraphs 1-112 of this Complaint.

120.

At all times herein mentioned BILL HOOVER and SHELIA HOOVER were husband and wife.

121.

As a direct result of Defendant's aforesaid conduct, Plaintiff BILL HOOVER suffered a

loss of love, affection, solace, moral support and physical assistance in the operation and maintenance of the home, all to his general damage in an amount within the jurisdiction of this Court.

WHEREFORE, Plaintiffs BILL HOOVER and SHELIA HOOVER pray for judgment against Defendant as hereinafter set forth.

TWELFTH CAUSE OF ACTION
ON BEHALF OF MARSHALL BRICE BOYLAN

[Loss of Consortium]

122.

Plaintiff MARSHALL BRICE BOYLAN hereby incorporates by reference as if fully set forth herein, each and every allegation contained in paragraphs 1-112 of this Complaint.

123.

At all times herein mentioned MARSHALL BRICE BOYLAN and SHERRY BOYLAN were husband and wife.

124.

As a direct result of Defendant's aforesaid conduct, Plaintiff MARSHALL BRICE BOYLAN suffered a loss of love, affection, solace, moral support and physical assistance in the operation and maintenance of the home, all to his general damage in an amount within the jurisdiction of this Court.

WHEREFORE, Plaintiffs MARSHALL BRICE BOYLAN and SHERRY BOYLAN pray for judgment against Defendant as hereinafter set forth.

THIRTEENTH CAUSE OF ACTION
ON BEHALF OF LAWRENCE BELLOW

[Loss of Consortium]

125.

Plaintiff LAWRENCE BELLOW hereby incorporates by reference as if fully set forth herein, each and every allegation contained in paragraphs 1-112 of this Complaint.

///

126.

At all times herein mentioned LAWRENCE BELLOW and FANNIE BELLOW were husband and wife.

127.

As a direct result of Defendant's aforesaid conduct, Plaintiff LAWRENCE BELLOW suffered a loss of love, affection, solace, moral support and physical assistance in the operation and maintenance of the home, all to his general damage in an amount within the jurisdiction of this Court.

WHEREFORE, Plaintiffs LAWRENCE BELLOW and FANNIE BELLOW pray for judgment against Defendant as hereinafter set forth.

FOURTEENTH CAUSE OF ACTION
ON BEHALF OF THOMAS CRAIN

[Loss of Consortium]

128.

Plaintiff THOMAS CRAIN hereby incorporates by reference as if fully set forth herein, each and every allegation contained in paragraphs 1-112 of this Complaint.

129.

At all times herein mentioned THOMAS CRAIN and CYNTHIA CRAIN were husband and wife.

130.

As a direct result of Defendant's aforesaid conduct, Plaintiff THOMAS CRAIN suffered a loss of love, affection, solace, moral support and physical assistance in the operation and maintenance of the home, all to his general damage in an amount within the jurisdiction of this Court.

WHEREFORE, Plaintiffs THOMAS CRAIN and CYNTHIA CRAIN pray for judgment against Defendant as hereinafter set forth.

WHEREFORE Plaintiffs pray for judgment as follows:

Plaintiff JULIE KRASAUSKAS:

1. For general damages in a sum within the jurisdiction of this Court;
2. For medical, hospital, and incidental expenses, according to proof;
3. For loss of earnings and for loss of earning capacity, according to proof;
4. For costs of suit;
5. For punitive or exemplary damages;
6. For such other relief as the Court deems just and proper.

Plaintiff WILLIAM KRASAUSKAS:

1. For loss of consortium and marital support, according to proof.

Plaintiff SHANNON GRAY:

1. For general damages in a sum within the jurisdiction of this Court;
2. For medical, hospital, and incidental expenses, according to proof;
3. For loss of earnings and for loss of earning capacity, according to proof;
4. For costs of suit;
5. For punitive or exemplary damages;
6. For such other relief as the Court deems just and proper.

Plaintiff JENNIFER DEGEARE:

1. For general damages in a sum within the jurisdiction of this Court;
2. For medical, hospital, and incidental expenses, according to proof;
3. For loss of earnings and for loss of earning capacity, according to proof;
4. For costs of suit;
5. For punitive or exemplary damages;
6. For such other relief as the Court deems just and proper.

Plaintiff COREY DEGEARE:

1. For loss of consortium and marital support, according to proof.

///

Plaintiff MARCEL HALL:

1. For general damages in a sum within the jurisdiction of this Court;
2. For medical, hospital, and incidental expenses, according to proof;
3. For loss of earnings and for loss of earning capacity, according to proof;
4. For costs of suit;
5. For punitive or exemplary damages;
6. For such other relief as the Court deems just and proper.

Plaintiff SHELIA HOOVER:

1. For general damages in a sum within the jurisdiction of this Court;
2. For medical, hospital, and incidental expenses, according to proof;
3. For loss of earnings and for loss of earning capacity, according to proof;
4. For costs of suit;
5. For punitive or exemplary damages;
6. For such other relief as the Court deems just and proper.

Plaintiff BILL HOOVER:

1. For loss of consortium and marital support, according to proof.

Plaintiff KAREN KING:

1. For general damages in a sum within the jurisdiction of this Court;
2. For medical, hospital, and incidental expenses, according to proof;
3. For loss of earnings and for loss of earning capacity, according to proof;
4. For costs of suit;
5. For punitive or exemplary damages;
6. For such other relief as the Court deems just and proper.

Plaintiff NICKOL HARSGRAVE:

1. For general damages in a sum within the jurisdiction of this Court;
2. For medical, hospital, and incidental expenses, according to proof;
3. For loss of earnings and for loss of earning capacity, according to proof;

4. For costs of suit;

5. For punitive or exemplary damages;

6. For such other relief as the Court deems just and proper.

Plaintiff PATSY SMITH:

1. For general damages in a sum within the jurisdiction of this Court;

2. For medical, hospital, and incidental expenses, according to proof;

3. For loss of earnings and for loss of earning capacity, according to proof;

4. For costs of suit;

5. For punitive or exemplary damages;

6. For such other relief as the Court deems just and proper.

Plaintiff TINA MARIE LEE:

1. For general damages in a sum within the jurisdiction of this Court;

2. For medical, hospital, and incidental expenses, according to proof;

3. For loss of earnings and for loss of earning capacity, according to proof;

4. For costs of suit;

5. For punitive or exemplary damages;

6. For such other relief as the Court deems just and proper.

Plaintiff SHERRY BOYLAN:

1. For general damages in a sum within the jurisdiction of this Court;

2. For medical, hospital, and incidental expenses, according to proof;

3. For loss of earnings and for loss of earning capacity, according to proof;

4. For costs of suit;

5. For punitive or exemplary damages;

6. For such other relief as the Court deems just and proper.

Plaintiff MARSHALL BRICE BOYLAN:

1. For loss of consortium and marital support, according to proof.

///

Plaintiff FANNIE BELLOW:

1. For general damages in a sum within the jurisdiction of this Court;
2. For medical, hospital, and incidental expenses, according to proof;
3. For loss of earnings and for loss of earning capacity, according to proof;
4. For costs of suit;
5. For punitive or exemplary damages;
6. For such other relief as the Court deems just and proper.

Plaintiff LAWRENCE BELLOW:

1. For loss of consortium and marital support, according to proof.

Plaintiff CYNTHIA CRAIN:

1. For general damages in a sum within the jurisdiction of this Court;
2. For medical, hospital, and incidental expenses, according to proof;
3. For loss of earnings and for loss of earning capacity, according to proof;
4. For costs of suit;
5. For punitive or exemplary damages;
6. For such other relief as the Court deems just and proper.

Plaintiff THOMAS CRAIN:

1. For loss of consortium and marital support, according to proof.

DATED: January 31, 3012

HERSH & HERSH
A Professional Corporation

By _____
Mark E. Burton, Jr.
Attorneys for Plaintiffs

HERSHANDHERSH
A Professional Corporation

EXHIBIT B

HERSH AND HERSH

April 2, 2012

VIA CERTIFIED MAIL-RETURN RECEIPT REQUESTED

RECEIVED
APR 04 2012
Via: Certified Mail
By: K. Mason

Anthony P. Bihl III
Group President, AMS
AMS World Headquarters
10700 Bren Road West
Minnetonka, MI 55343

Re: Krasauskas, et al. v. American Medical Systems, Inc.
San Francisco Superior Court Case No.: CGC-11-517793

Dear Mr. Bihl:

Service of process is being made upon you on behalf of American Medical Systems, Inc., pursuant to §415.40 of the California Code of Civil Procedure. Please sign and return the enclosed Notice and Acknowledgment of Receipt in the self-addressed, stamped envelope provided.

Enclosed please find the Summons, Complaint and Demand for Jury Trial, Civil Case Cover Sheet, Notice to Plaintiff, Alternative Dispute Resolution (ADR) Program Information Package, and Mediation Services Flyer. Please immediately furnish these documents to your insurance carrier or attorneys.

Very truly yours,

Amy Eskin

AE:pg
Encl.

POS-015

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):	FOR COURT USE ONLY
Amy Eskin (State Bar No. 127668) Hersh & Hersh, 601 Van Ness Avenue, Suite 2080 San Francisco, CA 94102 TELEPHONE NO.: 415-441-5544 FAX NO. (Optional): E-MAIL ADDRESS (Optional): ATTORNEY FOR (Name): Plaintiffs JULIE KRASAUSKAS, et al.	
SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO STREET ADDRESS: 400 McAllister Street MAILING ADDRESS: CITY AND ZIP CODE: San Francisco, CA 94102 BRANCH NAME:	
PLAINTIFF/PETITIONER: JULIE KRASAUSKAS, et al. DEFENDANT/RESPONDENT: AMERICAN MEDICAL SYSTEMS, INC.	
NOTICE AND ACKNOWLEDGMENT OF RECEIPT—CIVIL	CASE NUMBER: CGC-11-517793

TO (insert name of party being served): AMERICAN MEDICAL SYSTEMS, INC.

NOTICE

The summons and other documents identified below are being served pursuant to section 415.30 of the California Code of Civil Procedure. Your failure to complete this form and return it within 20 days from the date of mailing shown below may subject you (or the party on whose behalf you are being served) to liability for the payment of any expenses incurred in serving a summons on you in any other manner permitted by law.

If you are being served on behalf of a corporation, an unincorporated association (including a partnership), or other entity, this form must be signed by you in the name of such entity or by a person authorized to receive service of process on behalf of such entity. In all other cases, this form must be signed by you personally or by a person authorized by you to acknowledge receipt of summons. If you return this form to the sender, service of a summons is deemed complete on the day you sign the acknowledgment of receipt below.

Date of mailing: April 2, 2012

AMY ESKIN
(TYPE OR PRINT NAME)

▶ _____
(SIGNATURE OF SENDER—MUST NOT BE A PARTY IN THIS CASE)

ACKNOWLEDGMENT OF RECEIPT

This acknowledges receipt of ***(to be completed by sender before mailing)***:

1. ☑ A copy of the summons and of the complaint.
2. ☑ Other *(specify)*:
Civil Case Cover Sheet; Notice to Plaintiff; Alternative Dispute Resolution (ADR) Program Information Package; Mediation Services Flyer

(To be completed by recipient):

Date this form is signed:

_____
(TYPE OR PRINT YOUR NAME AND NAME OF ENTITY, IF ANY, ON WHOSE BEHALF THIS FORM IS SIGNED)

▶ _____
(SIGNATURE OF PERSON ACKNOWLEDGING RECEIPT, WITH TITLE IF ACKNOWLEDGMENT IS MADE ON BEHALF OF ANOTHER PERSON OR ENTITY)

Form Adopted for Mandatory Use
Judicial Council of California
POS-015 [Rev. January 1, 2005]

NOTICE AND ACKNOWLEDGMENT OF RECEIPT — CIVIL

Code of Civil Procedure,
§§ 415.30, 417.10
www.courtinfo.ca.gov

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